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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,943	03/08/2000	KUBER T. SAMPATH	CIBT-P01-570	7342

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EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/423,943	SAMPATH ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-29 and 76 is/are pending in the application.
- 4a) Of the above claim(s) 5,29 and 76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 6-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 21 June 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/423943 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restrictions

2. Applicant's election with traverse of Group I and species election of renal tissue in Paper No. 24 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to search both groups, because the second group contains only two claims. This is not found persuasive because, as stated in the office action of paper no. 23, the inventions are distinct from each other, as is evidenced by their separate classification. They therefore require separate searches and separate considerations, regardless of the number of claims involved.

Applicant further indicates that, on allowance of a generic claim, Applicant is entitled to consideration of claims to additional species. This entitlement was acknowledged on p. 3 of the office action of paper no. 24. Applicant additionally states that "the burden is on the Examiner to examine the claims throughout their scope, together with any claims dependent thereon drawn to non-elected species". As stated above and in the previous office action, dependent claims drawn to other species will be considered if a generic claim is found allowable.

The requirement is still deemed proper and is therefore made FINAL. Claims 1, 3, 5-29, and 76 are pending in this application. Claims 29 and 76 are withdrawn from consideration as being drawn to a non-elected invention. Claim 5 is withdrawn from consideration as drawn to a non-elected species.

Specification

3. The amendment filed 21 June 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The term "non-neuronal" does not appear in the specification as originally filed. While many different tissue types are contemplated, there is nothing in the original specification that provides support for a group of tissues specifically excluding neural tissue.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3, 6, and 8-22, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. As stated above, there is no support in the specification for "non-neuronal" tissue. There is nothing to indicate to one of skill that Applicant contemplated a group of tissue types specifically excluding neural tissue.

6. Claims 1, 3, and 8-28 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of screening for BMP-related factors, does not

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reasonably provide enablement for screens for morphogens as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

These claims are drawn to methods of screening for morphogens. Applicant indicates that "morphogens" encompasses members of the TGF- β superfamily. However, the art teaches that TGF- β itself is implicated in kidney disease. See, for example, Kumar et al., *American J. Physiology*, 1994, vol. 266, pp F829-F832. Kumar et al. suggests blocking TGF- β as a means of treating kidney disease (p. F838, column 1). Thus one of skill in the art could not predictably use Applicant's invention as broadly claimed to identify and assess morphogens as broadly claimed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3, 6, and 8-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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These claims are drawn to methods of identifying morphogens or analogs thereof.

"Analog" are not defined in the specification and one of skill in the art would not know what molecules were encompassed. Claims 23 and 25 are indefinite in the recitation of "variants".

Applicant has not defined such variants; one of skill would not know what degree of alteration would be considered a variation.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 6, 12-15, 20, and 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/04692, Kuberasampath et al.

WO 93/04692 teaches models for evaluating morphogens *in vivo* in surgically-induced renal ischemia-reperfusion injury, followed by parental administration of the morphogen, on p. 77, anticipating the limitations of claims 1, 6, 12, 15, 20, and 23-28. That these morphogens include those claimed by Applicant is set forth in table II, pages 44-49. Intravenous administration is taught in a cardiac model on pp. 70 and 73, anticipating claim 13. Oral administration is taught on p. 81, anticipating claim 14. WO 93/04692 also teaches other means of administration on p. 51.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 8-11, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/04692. WO 93/04692 teaches as set forth above but fails to teach dosage optimization, as claimed in claim 3, or evaluation in compromised animals, as claimed in instant claims 8-11, 21 and 22. However, it would have been obvious to one of ordinary skill to evaluate treatment parameters such as time of administration and administration to compromised animals.

Optimization of treatment protocols is art standard: Benet and Sheiner, for example, teach conditions including age and disease as affecting drug administration (in Goodman and Gilman's The Pharmacological Basis of Therapeutics, 6th edition, 1980, p. 1685). Further, WO 93/04692 teaches evaluation of administration "at various times prior to or following occlusion and/reperfusion". Evaluation of morphogens in fibrosis is taught in an *in vitro* model on pp. 83-86. Dosage optimization is addressed on p. 59. WO 93/04692 thus teaches a model for evaluating the effects of morphogens on renal damage, and further teaches several factors important for therapeutic administration. Thus it would have been obvious to one of ordinary skill to evaluate morphogens using the method of WO 93/04692 at different times, in different

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doses, and in different disease states; one of ordinary skill would have been motivated to do so because WO 93/04692 explicitly suggests different time points, doses, and means of administration, and because altered effects in disease states are well known in the art, as taught by Benet and Sheiner. Thus one of ordinary skill would have readily perceived that these parameters should be evaluated in the model taught by WO 93/04692.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

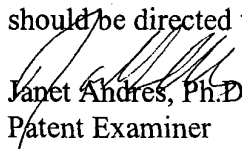
Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly

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set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Janet Andres, Ph.D.
Patent Examiner

June 13, 2003